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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,198	02/10/2005	Petrus Johannes Maria Nuijten	I-2002.013 US	3848

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EXAMINER	
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ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
01/16/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,198	NUIJTEN ET AL.	
	Examiner	Art Unit	
	Khatol S. Shahnan-Shah	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 October 2008 and 20 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7,9 and 10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7,9 and 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

RESPONSE TO AMENDMENT

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.Applicants' submission filed on 9/11/2008 has been entered. Claim 8 has been canceled. Claim 7 has been amended.
2. Claims 7, 9 and 10 are pending and under consideration.

Objections Maintained

3. Objection to the specification in regard to sequence compliance made in paragraph 5 of the office action mailed 10/03/2007 is maintained. Applicant has amended the specification to include sequence identifiers submitted, however, the CRF submitted with the replacement sequence listing was flawed technically and not entered into the database. The new CRF submitted 10/20/2008 is also flawed technically and not entered into the database. Although an examination of this application on the merits can proceed without prior compliance, compliance with the Sequence Rules is required for the response to this Office action to be complete. Applicants must correct the sequence submissions in the mentioned claims. See attached sequence listing comments.

Rejections Moot

4. Rejection of claim 8 under 35 U.S.C. 112 first paragraphs, made in paragraph 7 of office action mailed 10/03/2007 is moot in view of cancellation of said claim.
5. Rejection of claim 8 under 35 U.S.C. 102 (b), made in paragraph 8 of office action mailed 10/03/2007 is moot in view of cancellation of said claim.

Rejections Withdrawn

6. Rejection of claims 7 and 9 under 35 U.S.C. 112 first paragraphs, made in paragraph 7 of office action mailed 10/03/2007 is withdrawn due to amendment of 9/11/2008.

7. Rejection of claim 10 under 35 U.S.C. 112 first paragraphs, made in paragraph 9 of office action mailed 05/13/2008 is withdrawn due to amendment of 9/11/2008.
8. Rejection of claims 7, 9 under 35 U.S.C. 102 (b), made in paragraph 8 of office action mailed 10/03/2007 is withdrawn due to amendment of 9/11/2008.
9. Rejection of claim 10 under 35 U.S.C. 102 (b), made in paragraph 10 of office action mailed 05/13/2008 is withdrawn due to amendment of 9/11/2008.

New Rejections

Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
11. Claim 7, 9 and 10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claim 7 recites an immunogenic fragment having a length of at least 33 amino acids of a 22.5 KD protein of *Streptococcus uberis.* The specification recites "Again another embodiment of the present invention relates to the use of a 22.5 kD *Streptococcus uberis* protein, or an immunogenic fragment of that protein having a length of at least 6 amino acids, wherein that protein or immunogenic fragment thereof has an amino acid sequence homology of at least 70%, preferably 80%, more preferably 85% with the amino acid sequence as depicted in SEQ ID NO: 2 for the manufacturing of a vaccine for combating Streptococcus uberis infection. The specification fails to provide information in regard to an immunogenic fragment having a length of at least 33 amino acids. *Streptococcus uberis* genome *DNA and* its proteins

are known in the art for example see Jayarao et al and Leigh et al. (Prior art of recode) However, these references are silent about variant amino acid sequences from these claimed proteins.

The Guidelines for the Examination of Patent Application Under 35 U.S.C. 112, 1st paragraph "Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant, identifying characteristics, i.e. structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in the position of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 3rd column).

Since the disclosure fails to describe the common attributes or characteristics that identify the members of the genus, and because the genus is highly variant, SEQ ID NO: 2 are insufficient to describe the fragments thereof. Adequate written description requires more than a mere statement that is part of the invention and a reference to a potential method of isolating it. The protein itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. LTS*. 18 USPQ 2d 1016. Applicant is directed to the Revised Interim Guidelines for the Examination of Patent Application under 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 64, No.244, pages 71427-71440, Tuesday December 21, 1999.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the

conclusion that the applicant was in possession of the claimed species is sufficient." MPEP 2163.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In Regents of the University of California v. Eli Lilly & Co., the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials. Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606; In re Smythe, 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain, species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus...."). Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. The MPEP does state that for generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not define what constitute a sufficient number of representatives, the Courts have indicated what do not constitute a representative number species to adequately describe a broad generic. In Gostelli, the Court determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. In re Gostelli, 872 F.2d at 1012, 10 USPQ2d at 1618.

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

13. Claims 7, 9 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as
the invention.

Claim 7 recite, "amino acid sequence depicted in SEQ ID NO: 2". This is vague and unclear. It is best if it recites "amino acid sequence comprising SEQ ID NO: 2".

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

15. Claims 7, 9 and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Bolton et al. (US 2003/0082781 A1) .

The claims are drawn to an immunogenic fragment of a *Streptococcus uberis* protein having at least 33 amino acid .

Bolton et al. teach isolated immunogenic proteins from Streptococcus species including *Streptococcus uberis* for immunization of dairy cattle against streptococcus infection (see title, abstract and claims specifically claim 1). These proteins are isolated from cell extract (see page 11). The *Streptococcus uberis* protein comprises an amino

acid sequence of 1-336 amino acid (see SEQ ID NO:8) Bolton recites immunogenic amino acid fragments comprising at least 5 amino acids (see claim 1, part f). The immunogenic fragment of at least 33 amino acid would be inherent in the proteins taught by Bolton et al.

Status of Claims

16. No claims are allowed.

Conclusion

17. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol Shahnan-Shah whose telephone number is (571)-272-0863. The examiner can normally be reached on Mondays and Wednesdays from 12:30-6:30 PM and Thursdays from 12:30-4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert B. Mondesi can be reached on 571-272-0956.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Khatol Shahnan-Shah
Art Unit 1645
January 12, 2009

/Robert B Mondesi/
Supervisory Patent Examiner, Art Unit 1645